REMARKS

Claims 16, 18, 21-26, and 32-48 are pending in the application and stand rejected. Claims 37-48 have been canceled herein to remove non-elected aspects of the invention. Claim 35 has been amended to correct a misspelling. No new matter has been added.

Applicant respectfully requests entry of the above amendments, which raise no new issues that would require further search and/or consideration, and which place the application in better condition for allowance or appeal.

In the light of the above claim cancellations and the following remarks, Applicant respectfully requests reconsideration and allowance of the pending claims.

Examiner Interview

Applicant thanks the Examiner for the courtesy of the telephonic interview of July 13, 2010, during which the outstanding rejections under 35 U.S.C. §§ 102 and 103 and the present claims were discussed.

Rejection Under 35 U.S.C. § 102

The Examiner rejected claims 16, 18, 21-26, and 36 under 35 U.S.C. § 102(e) as anticipated by Erickson-Miller et al. (U.S. Pub No. 2007/0105824) (hereinafter "Erickson-Miller").

Erickson-Miller discusses the use of non-peptide thrombopoeitin (TPO) receptor agonists for the treatment of a very broad range of conditions, including epilepsy, perinatal asphyxia, glaucoma, AIDS, and male pattern baldness (See, e.g., ¶¶ 271, 274, 276 and 277 of Erickson-Miller). Apparently recognizing that the diseases cited are caused by different mechanisms and fall into distinct categories, Erickson-Miller suggests that non-peptide TPO agonists can be co-administered with other agents for the treatment of different groups of conditions. Thus, ¶ 298 suggests that diseases caused by excessive bone loss (which had been characterized in ¶ 275 as including periodontal disease and gingivitis) could be treated with non-peptide TPO agonists co-

administered with compounds active against excessive bone loss or cartilage or matrix degradation such as bisphosphonates. GM-CSF is not known, and was not suggested, as being able to treat excessive bone loss or cartilage or matrix degradation.

Separately, Erickson-Miller states in ¶ 308 that non-peptide TPO agonists can be used in conjunction with GM-CSF and "other molecules identified as having anti-apoptopic, survival or proliferative properties for stem cells, progenitor cells, or *other cells expressing TPO receptors*" (emphasis added). Gingival cells are not known to express TPO receptors. Further, claims 15 and 16 of the Erickson-Miller patent describes the co-administration of GM-CSF and a non-peptide TPO agonist with GM-CSF acting as a "hematopoietic-cell mobilizing agent." These claims are distinct from Erickson-Miller's claim 29, describing the co-administration of a non-peptide TPO agonist and agents that are used for the treatment of excessive bone loss, including bisphosphonates, for gingivitis and periodontal disease.

Thus, Erickson-Miller teaches the co-administration of GM-CSF with a non-peptide TPO agonist for situations involving mobilizing hematopoietic cells and cells expressing TPO receptors but teaches the use of a different class of molecules for conditions classified as involving excessive bone loss, including periodontal disease and gingivitis.

Applicant's independent claim 16 recites the local administration of GM-CSF by injection in the proximity of the periodontal disease. Erickson-Miller suggests, in ¶ 294, that with regards co-administration of a non-peptide TPO agonist and another compound, "it does not matter if the compounds are administered in the same form, e.g. one compound may be administered topically and another compound may be administered orally." Erickson-Miller does not, however, teach that GM-CSF should be locally injected in the proximity of periodontal disease. Prior reference to generic routes of administration does not anticipate the claim to a highly specific route of administration. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.").

Claims may be properly rejected as anticipated under § 102 "if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). Erickson-Miller does not expressly refer to the local administration of GM-CSF for the treatment of a periodontal disease. A

claimed characteristic is inherently present in a prior art reference if "that missing characteristic is necessarily present, or inherent, in [a] single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005). Inherent anticipation still requires that all elements must be disclosed in an anticipatory reference in the same way as in the claim. *Therasense, Inc. v. Becton Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010); *see also Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) ("[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation.").

Erickson-Miller does not necessarily inherently disclose the use of GM-CSF for the treatment of periodontal disease, in fact it teaches the use of a different class of agents for conditions involving bone loss, nor does it necessarily inherently disclose the local administration of GM-CSF for the treatment of periodontal disease. For these reasons, Applicant respectfully requests withdrawal of the rejection of independent claim 16 and dependent claims 18, 21-26, and 36 under § 102 over Erickson-Miller.

Rejection Under 35 U.S.C. § 103

The Examiner rejected the remaining claims 21 and 32-35 as being unpatentable under 35 U.S.C. § 103(a) over Erickson-Miller in view of O'Uchi et al. (U.S. Patent No. 6,682,718) (hereinafter "O'Uchi").

O'Uchi teaches the treatment of periodontitis by the topical injection of bisphosphonates into periodontal tissues. The Examiner suggested that Erickson-Miller taught the use of GM-CSF for the treatment of periodontal disease and rendered Applicant's claims obvious in view of O'Uchi's description of local injection of therapeutic agents for the treatment of a periodontal disease. *See* Office Action of Dec. 28, 2009 at 8. Applicant believes that one of ordinary skill in the art would not have the motivation to combine these two references so as to render Applicant's claims obvious.

Applicant agrees that one of ordinary skill in the art would have been motivated to combine O'Uchi's description of the local administration with Erickson-Miller's suggestion at ¶ 298 to utilize compounds known to be effective in the treatment of bone loss, including bisphosphonates, estrogen and androgen receptor modulators, inhibitors of osteoclast proton

ATPase, inhibitors of HMG-CoA reductase, integrin response antagonists or osteoblast anabolic agents. Indeed, O'Uchi explicitly describes the local injection of bisphosphonates, reinforcing Erickson-Miller's teaching that non-peptide TPO receptor agonists can be used with bisphosphonates in the treatment of periodontal disease.

In contrast, Erickson-Miller discusses the use of GM-CSF in the context of "anti-apoptotic, survival or proliferative properties for stem cells, progenitor cells, or other cells expressing TPO receptors" (¶ 308) and "hematopoietic-cell mobilizing agent[s]" (claims 15-16). Neither Erickson-Miller nor O'Uchi suggests that GM-CSF should be used for the treatment of a periodontal disease.

The determination of obviousness involves identifying a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way that the claimed invention does. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356–57 (Fed. Cir. 2007). As long as it is not applied as a "rigid rule," looking for a teaching, suggestion, or motivation to combine prior art references can guide the obviousness inquiry. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402 (2007).

By suggesting the use of non-peptide TPO receptor agonists and bisphosphonates for the treatment of a periodontal disease, but suggesting the use of non-peptide TPO receptor agonists and GM-CSF for treatment of conditions related to hematopoietic cell mobilization, stem cells and cells expressing TPO receptors, the combination of Erickson-Miller and O'Uchi teaches away from the use of non-peptide TPO receptor agonists and GM-CSF for treatment of periodontal disease. That is, one of ordinary skill in the art would not find in Erickson-Miller a motivation to treat a disease such as periodontal disease with GM-CSF and, in fact, would have been motivated to follow O'Uchi and inject bisphosphonates locally in periodontal tissues along with non-peptide TPO receptor agonists. For this reason, and reasons of record, Applicant respectfully requests withdrawal of the rejection of claims 21 and 32–35 under § 103 over Erickson-Miller in view of O'Uchi.

CONCLUSION

In light of the above, Applicant respectfully submits that the present claims are in condition for allowance, which action is requested. If the Examiner feels that it would further

prosecution or expedite allowance of the present case, he is invited to telephone the undersigned at 612-337-2506.

No fees are believed to be due. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date:July 21, 2010_____

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